A I D S TREATMENT N E W S

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Contents

AIDS Treatment News

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Statement of Purpose:

AIDS Treatment News reports on experimental and standard treatments, especially those available now. We interview physicians, scientists, other health professionals, and persons with AIDS or HIV; we also collect information from meetings and conferences, medical journals, and computer databases. Long-term survivors have usually tried many different treatments, and found combinations that work for them. *AIDS Treatment News* does not recommend particular therapies, but seeks to increase the options available.

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The IOM released a 150-page report concluding that the study was properly conducted and its results are valid.

DHEA Access Threatened?.....

DHEA came close to being totally banned in the U.S. in January 2005, when a new law aimed at steroids in sports took effect. Even doctors would not have been able to prescribe DHEA, and medical research on its uses would have become far more difficult. A potentially important treatment could have been lost for a long time -- and could still be lost unless people are vigilant.

Involuntary Weight Loss: Interview with Lisa Capaldini, M.D.

by John S. James

On April 19, 2005 we spoke to Lisa Capaldini, M.D., an HIV specialist in San Francisco who alerted us to metabolic complications of HIV and antiretroviral treatment in 1997 (see *AIDS Treatment News* #277). We asked Dr. Capaldini for a brief overview of treating involuntary weight loss today.

Dr. Capaldini explained that a small but important group of patients is still wasting, although their HIV viral load is controlled. And a larger group has difficulty maintaining weight, due to queasiness, nausea, and anorexia (loss of appetite) with antiretroviral treatment. An additional problem is that if patients cannot eat, they cannot take some of their medications with food as required. So

involuntary weight loss can be a problem both for those with active wasting, and those who need help with antiretroviral side effects in order to be able to eat properly.

We noted a recent report on a new formulation of Megace (megestrol acetate), an appetite stimulant, to improve its absorption [1] -- and asked about the reputation of megace for putting on weight by increasing fat and water -- not helpful when the problem is muscle wasting. Dr. Capaldini agreed that this is a relevant concern. But as she explains to her patients, there are two issues: the body must get enough calories, and then must use them properly.

She noted that some doctors make the mistake of just giving Oxandrin (oxandrolone, an anabolic steroid, which helps build muscle mass), when the real problem is that the patient will not eat. Instead, these patients need an appetite stimulant, such as Megace, or Marinol -- and then a separate assessment of whether there is a lack of lean body mass. One cannot reliably tell just by looking whether someone has too little lean body mass. Dr. Capaldini uses BIA (bioelectric impedance) to help determine whether this is the case.

We asked about the common belief that men using megace may need treatment with testosterone as well. Dr. Capaldini explained that there are two situations where this is true. Rarely, megace may cause adrenal dysfunction. And much more commonly, many patients who are being treated for weight loss have low testosterone already, and need treatment for it.

Dr. Capaldini noted that oxandrolone (used for treating muscle wasting) is a pure anabolic -- it helps increase muscle mass, but does not have any androgenic (masculinizing) effect at all (this is why women can take the full dose). In fact, oxandrolone can cause lower levels of testosterone. Therefore many studies of oxandrolone now give testosterone to help get everybody to a certain baseline level. Dr. Capaldini believes that all patients with HIV-associated weight loss should be screened for low testosterone (hypogonadism) and for depression.

Dr. Capaldini noted that just as there is no right antiretroviral for everyone, nutritional problems also can be multifactorial. Different patients may need very different approaches.

She also noted that for many people with HIV, HAART treatment (and medications to treat HAART side effects) will be lifelong; therefore it is important that these treatments be flexible and easy to use. This is why the new version of Megace is now being tested. [1] The current formulation can be a problem, because it is an appetite stimulant, yet must be taken with food in order to be absorbed well by the body. The new formulation (still experimental; it could be available as early as mid summer 2005) has a much smaller particle size so that it can dissolve better, even when the patient has not been able to eat.

References

1. RA Femia. Megestrol acetate nanocrystal oral suspension: results of dose-escalating studies under fed and fasting conditions. AmfAR National HIV/AIDS Update Conference, April 10 - April 13, 2005 in Oakland, California, http://www.amfar.org/nauc.

Medicaid Cuts Alert

by John S. James

Huge cuts in medical care for the poorest and sickest patients could happen in many or all states, if Federal and state governments try to save money by imposing arbitrary caps and co-pays. (Medicaid is called different names in different states, such as Medi-Cal in California, or Medical Assistance in Pennsylvania.) Everyone knows that there is waste throughout U.S. health care. The problem is that most of the political proposals are all about saving money by numerical quotas or prices that arbitrarily cut needed care, not about improving the system.

For example, doctors as well as patients fear a cap on the number of prescriptions, because it will force doctors to choose which needed prescriptions to omit -- making them practice substandard medicine (or close their eyes and let their patients practice it on themselves) if many people are to be treated at all. Large co-pays on prescription drugs will result in many people on Medicaid (who must be poor to qualify) not filling some or all of their prescriptions, resulting in more illness, drug resistance, and spread of infectious disease. New fees for laboratory tests will be charged against the doctor's office or clinic, which will likely have to cover the cost since their patients will not have the money -- a major problem for public or independent practices, which often operate on a very tight margin if they accept Medicaid patients at all.

There are better ways to save money. One idea is to require pre-authorization before paying for Viagra and other impotence medicines. Huge funds go into buying these expensive drugs, which are often abused. Doctors might welcome relief from pressure to write the prescriptions.

This strategy of finding critical areas of clear abuse that result in huge financial losses could be greatly helped by laws requiring more transparency in exactly how government health funds are spent. Today the real economics of health-care delivery is hidden by secret prices and deals.

But ultimately there is no simple solution, because Medicaid is a huge program, accounting for almost one in five of all U.S. healthcare dollar -- and it is the care of last resort,

paying for the people that private insurance and other systems don't want. Three quarters of the Medicaid beneficiaries are low-income children and their parents, and the rest are elderly or disabled -- and two thirds of Medicaid dollars are spent for nursing-home care, drugs, and other services for the elderly and disabled. Medicaid cost per person has grown less rapidly than the cost of private insurance -- but the number of people covered has grown as insurance companies have increasingly learned how exclude the people who need the most care. [1] AIDS is not particularly expensive compared with other major chronic diseases.

The bottom line is that it is not consistent with American values to abandon the most vulnerable people. We need to improve our healthcare system (one of the least cost-effective in the world) instead of managing financial problems by leaving illness untreated.

What You Can Do

Check with friends, or with AIDS and other organizations you respect, either locally or online, to find out how to get action alerts telling you when it is important to call Congress or your state government to protect Medicaid and other healthcare programs.

Note that phone calls and faxes are often better than letters to Congress, as anything sent in the mail may be delayed for two weeks or more for irradiation or other precautions against terrorist attack, especially during security alerts. Emails are used, but are problematic because email from constituents can be lost among the flood of mass emails sent to everybody in Congress.

Often a personal voice on the phone is best -- either to register your opinion on a current issue, or for a first contact if you have personal experience or expert information you want to share. There may be a local office, if the cost of calling Washington or the state capitol is an issue. Usually there are no official toll-free numbers for calling your representatives, although sometimes private organizations provide them (in which case they will receive the number you called from, when they are billed). In our experience, long waits on hold have been rare -- though sometimes it will take several calls to get through the busy signal, so a Redial button may help. Almost always the calls are brief once you do reach the office. Be polite; if you live in the official's state or district let the person you are speaking with know that; and make sure it is clear what issue you are calling about, and which side you are on.

References

1. For background on Medicaid and other current health issues, see the Kaiser Family Foundation, http://www.kff.org. Our reference above is to an "Ask the Experts" Webcast of April 20, 2005, archived both in video and as a transcript on the site.

Adult HIV Treatment

Guidelines Updated

On April 7 the U.S. guidelines for antiretroviral treatment were updated to reflect new information on drug interactions and toxicities, and to include a new table on expanded access to antiretrovirals not yet approved (currently the only one available through such a program is tipranavir). The current official U.S. HIV guidelines are always online at the AIDSinfo site published by the U.S. Department of Health and Human Services, http://www.aidsinfo.nih.gov/ (you need to click on the proper category listed on the left of the page, then click again to download the document you want in the format desired -- usually PDF). [Note: now that the nonocccupational exposure document (what to do if the condom breaks, etc.) is official, it is available on this site as well.]

On April 8 the U.S. Food and Drug Administration (FDA) published the following description of the changes made in the current revision:

> The *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents* has been revised to include up-to-date drug information, including updated information on nevirapine hepatotoxicity risks, the interaction between rifampin and ritonavir-boosted saquinavir, new pregnancy data for efavirenz, and new contraindications and warnings for ritonavir and lopinavir/ritonavir use. Also included in the updated document is a new table, Table 30, providing information on the tipranavir expanded access program.
>
> All changes to the document are highlighted in yellow.
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> The updated guidelines document is available at the AIDSinfo Web site at: http://www.aidsinfo.nih.gov/.
> You can view, order hard copies of the guidelines, or request them by email at the web site.
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> The AIDSinfo website is also a useful source of other information related to HIV/AIDS, including other treatment and prevention guidelines, downloadable databases for PDAs (Personal Digital Assistants), and HIV/AIDS-related clinical trials information.

In-Depth Medical Reports on the Retroviruses Conference

The Clinical Care Options HIV site, http://www.clinicaloptions.com/hiv/, now has six training modules (as of April 26) for HIV physicians (but open to anyone, after free registration on the site) on new information presented at the Retroviruses conference, February 22-25, 2005, in Boston. Each module consists of a collection of discussions on different subtopics, between three leading experts. To assist the discussions, "capsule summaries" present details in an outline format, so that the experts can focus on what's most

important for readers to know, without having to recite the details since those are already available.

Each of the six modules provides two hours of CME (continuing medical education) credit for physicians. Non-physicians may find the presentations difficult, because of the background knowledge they assume. But patients may find useful and understandable information about issues that matter to them.

The six modules are:
* Management of Treatment-Naive Patients
* Resistance and Management of Experienced Patients
* Investigational Antiretroviral Agents
* Pharmacology and Adverse Drug Effects
* Hepatitis Coinfection and Opportunistic Infections
* Metabolic Complications and Lipodystrophy

IOM: Nevirapine Study Is Reliable

by John S. James

Due to questions raised about HIVNET 012, the groundbreaking study that first showed that single-dose nevirapine could reduce transmission of HIV from infected mothers to their babies, the prestigious Institute of Medicine reviewed the study at the request of the U.S. National Institutes of Health, and presented an independent assessment. It concluded that the study was conducted ethically, that the findings that nevirapine is safe and effective for preventing maternal transmission were well supported, and that policy makers and scientists can rely on the resulting data and conclusions. [1, 2]

The IOM report will be published in a document of about 150 pages, including an executive summary of about 7 pages. Meanwhile, an uncorrected proof of the executive summary and complete report are available online. [2]

References

[1] Press release from the Institute of Medicine, April 7, 2005,

http://www.iom.edu/report.asp?id=26287 (click on "Press Release").

[2] Complete report, *Review of the HIVNET 012 Perinatal HIV Prevention Study*, http://books.nap.edu/catalog/11264.html.

[3] For a report from the public press briefing of November 8, see Jennifer Couzin, "IOM Panel Clears HIV Prevention Study," *Science*, April 15, 2005, volume 308, issue 5720, page 334.

DHEA Access Threatened?

by John S. James

DHEA is the most abundant hormone in the human body. Blood levels peak in early adulthood, around age 20, and then decline greatly during the human lifespan, falling by about 80% in the elderly. Blood levels also decline in many illnesses. Human studies of DHEA supplementation to restore normal levels are promising; for example, a recent small but careful study, *not* in persons with HIV, found that DHEA was an effective treatment for midlife-onset major and minor

depression in both men and women [1].

But there has never been a large, long-term, placebo-controlled trial -- and most doctors want more information before accepting DHEA treatment in standard medical practice. No one is expecting such a trial, because DHEA has long been used so it cannot be patented; therefore no pharmaceutical company will pay for the research, because it could not recoup its investment later by charging monopoly prices. (Governments or nonprofit organizations can in theory develop drugs, but the U.S. system does not encourage that -- and other countries spend far less than the U.S. on medical research overall.) Meanwhile, DHEA has been sold over the counter in U.S. drugstores and health-food stores for years. It is used mostly by the elderly, and by others whose blood level is low. Standard tests for blood levels are routinely available to doctors.

DHEA is chemically an anabolic steroid (in the body it is changed to androstenedione, famous for use by baseball players and other athletes, which in turn is changed into testosterone). But DHEA has not been used by bodybuilders, probably because it is not effective for that purpose; most healthy young people have plenty of DHEA already, and indications are that supplementation helps only by correcting a deficiency, bringing DHEA blood levels into the upper part of the normal range.

Recently Congress passed a law to prohibit androstenedione and other substances that can turn into testosterone or similar steroids in the body; the ban took effect on January 20, 2005. It regulates those substances as anabolic steroids under the control of the DEA (Drug Enforcement Administration). If DHEA had been included, no one in the U.S. could use it, not even with a doctor's prescription. What saved DHEA in this country was the work of Senator Orrin Hatch (Republican of Utah), who refused to support the bill unless DHEA was exempted, and a few others including Senator Tom Harkin (Democrat of Iowa).

The AIDS community, like almost all of the public, was not involved when this legislation was going through Congress, probably because we did not know about it. According to members of Congress quoted in a recent article in The *New York Times* [2], the only opposition to banning DHEA came from the supplements industry -- while members of Congress who wanted to leave DHEA on the market did not see any significant opposition to doing so.

Comment

What happened here is that a substance with potential uses in HIV, aging, depression, and other conditions was almost banned incidentally, just because it is chemically a steroid, even though it has not been used for bodybuilding. DHEA has not had the systematic research necessary to develop a drug because it is unpatentable, and therefore could not be sold at high prices. Control by the DEA would have made the research far more difficult, by demonizing the drug